UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Caswell # 889

DATE: September 27, 1979

SUBJECT: Free Standing Summary of PP # 9F2172. Request for tolerance for trifluralin in or on Barley and Sorghum; Request for a "grain crop group" tolerance at 0.05 ppm. EPA Reg. No. 1471-35.

FROM: Roland A. Gessert, D.V.M.; Toxicology Branch
Roland A. Gessert

TO: Dr. Willa Garner, Product Manager # 23.

WSW 10-4-79

THRU: Dr. Adrian Gross, Chief, Toxicology Branch

PETITIONER: Elanco Products Company
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RECOMMENDATIONS:

1. The requested tolerances can be toxicologically supported. No-effect levels considered in setting the tolerances are summarized below:

2000 ppm	-	Rat, 2-year feeding study (2 studies)
200 ppm	-	Rat, 4-generation reproduction study
2000 ppm	-	Rat, continuous breeding (approximately 8 litters from each female)
400 ppm	-	Dog, 2-year feeding (2 studies)
400 ppm	-	Dog, 3-year feeding study
400 ppm	-	Dog breeding study
450 ppm	-	Rabbit teratology study

2. The toxicological profile of trifluralin is essentially complete. No data are currently lacking.

3. Tolerances for trifluralin have been established under 40 CFR 180.207.

4. The published tolerances utilize 0.72% of the ADI. Unpublished Toxicology Branch Approved tolerances and the current action have no significant effect on the ADI; all tolerances considered still lutilize only 0;72% of the ADI.

5. The ADI is based on the NEL of 400 ppm in the 3 long-term dog feeding studies, the most sensitive specie for which data are available. A 100-fold safety factor was used to calculate the ADI.

$$ADI = NEL \times \frac{1}{100}$$

$$ADI = 10 \text{ mg/kg/day} \times \frac{1}{100} = 0.1 \text{ mg/kg/day}$$

The MPI for a 60 kg person is 6 mg/day

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

6. Trifluralin is an RPAR candidate, probably due to the presence of N-nitroso-di-n-propylamine (NDPA) contaminant at concentrations of [redacted] ppm in the trifluralin used in the tests. Oncogenicity tests conducted by NCI with trifluralin technical chemical in rats and mice indicate the chemical is not oncogenic in rats nor in male mice. Hepatocellular carcinomas and alveolar/bronchiolar adenomas were observed in female mice (including controls), but the incidence appeared to be dose related.

Residue Chemistry Branch does not expect nitrosamines of trifluralin to cause residue problems.

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